IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM CORPORATION,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
DR. REDDY'S LABORATORIES LTD. and DR. REDDY'S LABORATORIES, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Corporation, by their undersigned attorneys, for their Complaint against Defendants, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc., hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiffs' JARDIANCE® (empagliflozin) tablets prior to the expiration of United States Patent No. 11,090,323.

THE PARTIES

2. Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Rd., Ridgefield, CT 06877.

3. Plaintiff Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

4. Plaintiff Boehringer Ingelheim Corporation ("BIC") is a corporation organized and existing under the laws of Nevada, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT, 06877.

5. BIPI, BII, and BIC are collectively referred to hereinafter as "Boehringer" or "Plaintiffs."

6. On information and belief, Defendant Dr. Reddy's Laboratories Ltd. ("DRL Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India.

7. On information and belief, DRL Ltd. controls and directs a wholly owned subsidiary in the United States named Dr. Reddy's Laboratories, Inc. ("DRL Inc."). DRL Inc. is a New Jersey corporation having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

8. DRL Ltd. and DRL Inc. are collectively referred to hereinafter as "DRL."

9. On information and belief, DRL Ltd. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States,

including within the state of Delaware, through its own actions and through the actions of its agents and subsidiaries, including DRL Inc., from which DRL Ltd. derives a substantial portion of its revenue.

10. On information and belief, DRL Inc. acted in concert with DRL Ltd. to prepare and submit ANDA No. 212336 (the "DRL ANDA") for DRL Ltd.'s 10 mg and 25 mg empagliflozin tablets ("DRL ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of DRL Ltd. Following FDA approval of the DRL ANDA, DRL Ltd. will manufacture and supply the approved generic products to DRL Inc., which will then market and sell the products throughout the United States at the direction, under the control, and for the direct benefit of DRL Ltd.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

12. Venue is proper in this Court because, among other things, each Defendant is a foreign corporation or the agent of a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c). Moreover, DRL has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware and has not contested venue in those cases. *See, e.g.*, *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 19-1495, D.I. 9 (D. Del. Sept. 4, 2019); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 18-779, D.I. 12 (D. Del. Jan. 11, 2019); *Novartis Pharmaceuticals Corporation v. Dr. Reddy's Laboratories Inc. et al.*, C.A. No. 22-498, D.I. 12 (D. Del. May 10, 2022). Further, DRL did not

contest venue, and filed counterclaims, in this District in the prior case in which Boehringer filed a lawsuit against DRL arising from DRL's submission of the DRL ANDA. *See Boehringer*, C.A. No. 19-1495, D.I. 9; *Boehringer*, C.A. No. 18-1779, D.I. 12.

PERSONAL JURISDICTION OVER DRL LTD.

13. Plaintiffs reallege paragraphs 1-12 as if fully set forth herein.

14. On information and belief, DRL Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

15. This Court has personal jurisdiction over DRL Ltd. because, *inter alia*, DRL Ltd., on information and belief: (1) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute DRL's infringing ANDA Products to residents of this State upon approval of ANDA No. 212336, either directly or through at least one of its wholly-owned subsidiaries or agents; (3) makes its generic drug products available in this State; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through DRL Inc.

16. On information and belief, DRL Ltd. has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g.*, *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 19-1495, D.I. 9 (D. Del. Sept. 4, 2019); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 18-1779, D.I. 12 (D. Del. Jan. 11, 2019); *Novartis Pharmaceuticals Corporation v. Dr. Reddy's Laboratories Inc. et al.*, C.A. No. 22-498, D.I. 12 (D. Del. May 10, 2022).

17. Alternatively, to the extent the above facts do not establish personal jurisdiction over DRL Ltd., this Court may exercise jurisdiction over DRL Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) DRL Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) DRL Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over DRL Ltd. satisfies due process.

PERSONAL JURISDICTION OVER DRL INC.

18. Plaintiffs reallege paragraphs 1-17 as if fully set forth herein.

19. On information and belief, DRL Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

20. This Court has personal jurisdiction over DRL Inc. because, *inter alia*, DRL Inc., on information and belief: (1) intends to market, sell, or distribute DRL's infringing ANDA Products to residents of this State; (2) is controlled by Defendant DRL Ltd. and is acting on behalf of DRL Ltd. with respect to the DRL ANDA; (3) makes its generic drug products available in this State; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

21. On information and belief, DRL Inc. has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g.*, *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 19-1495, D.I. 9 (D. Del. Sept. 4, 2019); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 18-1779, D.I. 12

(D. Del. Jan. 11, 2019); *Novartis Pharmaceuticals Corporation v. Dr. Reddy's Laboratories Inc. et al.*, C.A. No. 22-498, D.I. 12 (D. Del. May 10, 2022).

BACKGROUND

U.S. PATENT NO. 11,090,323

22. On August 17, 2021, the USPTO duly and legally issued United States Patent No. 11,090,323 ("the '323 patent") entitled "Pharmaceutical composition, methods for treating and uses thereof" to inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. A true and correct copy of the '323 patent is attached as Exhibit A. The '323 patent is assigned to BII. BIC and BIPI are licensees of the '323 patent.

JARDIANCE®

23. BIPI is the holder of New Drug Application ("NDA") No. 204629 for empagliflozin, for oral use, in 10 mg and 25 mg dosages, which is sold under the trade name JARDIANCE®.

24. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '323 patent is among the patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") with respect to JARDIANCE®.

25. The '323 patent covers the JARDIANCE® product and its use.

ACTS GIVING RISE TO THIS ACTION

COUNT I—INFRINGEMENT OF THE '323 PATENT AS TO THE DRL ANDA

26. Plaintiffs reallege paragraphs 1-25 as if fully set forth herein.

27. On information and belief, DRL submitted the DRL ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the DRL ANDA Products.

28. DRL has represented that the DRL ANDA refers to and relies upon the JARDIANCE® NDA and contains data that, according to DRL, demonstrate the bioavailability or bioequivalence of the DRL ANDA Products to JARDIANCE®.

29. Plaintiffs received a letter from DRL on or about July 21, 2022 stating that DRL was amending its ANDA to include a certification in the DRL ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '323 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the DRL ANDA Products (the "DRL Paragraph IV Certification"). DRL intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the DRL ANDA Products prior to the expiration of the '323 patent.

30. DRL has infringed at least one claim of the '323 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the DRL ANDA, by which DRL seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the DRL ANDA Products prior to the expiration of the '323 patent.

31. DRL has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the DRL ANDA Products in the event that the FDA approves the DRL ANDA. Accordingly, an actual and immediate controversy exists regarding DRL's infringement of the '323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

32. DRL's manufacture, use, offer to sell, or sale of the DRL ANDA Products in the United States or importation of the DRL ANDA Products into the United States during the term of the '323 patent would further infringe at least one claim of the '323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

33. On information and belief, the DRL ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '323 patent either literally or under the doctrine of equivalents.

34. On information and belief, the use of the DRL ANDA Products constitutes a material part of at least one of the claims of the '323 patent; DRL knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

35. On information and belief, the offering to sell, sale, and/or importation of the DRL ANDA Products would contributorily infringe at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

36. On information and belief, DRL had knowledge of the '323 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

37. On information and belief, the offering to sell, sale, and/or importation of the DRL ANDA Products by DRL would actively induce infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

38. On information and belief, DRL does not deny that the DRL ANDA Products will infringe the claims of the '323 patent. In the DRL Paragraph IV Certification, DRL did not deny that the DRL ANDA Products will infringe the claims of the '323 patent.

39. Plaintiffs will be substantially and irreparably harmed if DRL is not enjoined from infringing the '323 patent.

40. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against DRL and for the following relief:

a. A Judgment be entered that DRL has infringed at least one claim of the '323 patent by submitting the DRL ANDA;

b. That DRL, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '323 patent, and (ii) seeking, obtaining, or maintaining approval of the DRL ANDA until the expiration of the '323 patent or such other later time as the Court may determine;

c. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of DRL's ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '323 patent, including any extensions;

d. That Boehringer be awarded monetary relief if DRL commercially uses, offers to sell, or sells its proposed generic versions of JARDIANCE® or any other product that infringes or induces or contributes to the infringement of the '323 patent, within the United States, prior to the expiration of this patent, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

e. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

f. Costs and expenses in this action; and

g. Such other and further relief as the Court deems just and appropriate.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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